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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,802	02/09/2005	Mathias Locher	42804-212835	6177
26694	7590	10/04/2007		
VENABLE LLP P.O. BOX 34385 WASHINGTON, DC 20043-9998			EXAMINER BROOKS, KRISTIE LATRICE	
			ART UNIT 1616	PAPER NUMBER
			MAIL DATE 10/04/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.		Applicant(s)	
	10/523,802		LOCHER ET AL.	
	Examiner		Art Unit	
	Kristie L. Brooks		1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5-13,16 and 17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5-13,16 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application

1. Claims 1, 5-13 and 16-17 are pending.
2. New grounds of rejections necessitated by Applicants amendments.

Withdrawn Rejections/Objections

3. The disclosure was objected for the use of the trademark AVICEL[®] in this application. Applicant has amended the specification to identify the trademark. The amendment is found persuasive and the Examiner has withdrawn the objection.

5. Claims 14-15 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 14-15 were rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101.

Applicant has cancelled claims 14-15. The amendment is found persuasive and the Examiner has withdrawn the rejection.

6. Claims 1-4, 6-8, and 10-15 were rejected under 35 U.S.C. 102(e) as being anticipated by Barsig (US Pub No. 2003/00992706). Applicant has amended the

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claim to recite "loteprednol or pharmaceutically acceptable ester thereof and N-(3,5-dicholopyridin-4-yl)-2-[1-(4-fluorobenzyl)-5-hydroxy-1H-indol-3-yl]-2-oxoacetamide". The amendment does not read on the prior art and the Examiner has withdrawn the rejection.

7. Claims 1, 3, 5-6, 8 and 9 were rejected under 35 USC § 102(b) as being anticipated by Keller et al. Applicant has amended the claim to recite "loteprednol or pharmaceutically acceptable ester thereof and N-(3,5-dicholopyridin-4-yl)-2-[1-(4-fluorobenzyl)-5-hydroxy-1H-indol-3-yl]-2-oxoacetamide". The amendment does not read on the prior art and the Examiner has withdrawn the rejection.

New Grounds of Rejections Necessitated by Amendments

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claim 1, 5-13 and 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barsig (US Pub No. 2003/00992706) in view of Joensuu (US Pub No. 2006/0264443).

Applicant claims a composition comprising loteprednol or pharmaceutically acceptable ester thereof and N-(3,5-dicholopyridin-4-yl)-2-[1-(4-fluorobenzyl)-5-hydroxy-1H-indol-3-yl]-2-oxoacetamide.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Barsig teaches the combined administration of a PDE4 or PDE3/4 inhibitors, such as N-(3,5-dicholopyridin-4-yl)-2-[1-(4-fluorobenzyl)-5-hydroxy-1H-indol-3-yl]-2-oxoacetamide also known as AWD-12-281, roflumilast, cilomilast, and disease modifying anti-rheumatic drugs (DMARDs) such as budesonide and mometasone furoate for the treatment of diseases including rheumatoid arthritis, acute and chronic airway disorders of various origins (allergic bronchitis, bronchial asthma, emphysema, COPD), adult respiratory distress syndrome (ARDS), dermatoses (especially of proliferative, inflammatory and allergic type), for example (see the entire article, especially the abstract, page 1 paragraph [001],[0017]-[0018]; page 2 paragraph [0019]-[0022]; page 3 paragraph [0030]-[0032]; page 4 paragraph [0033]; page 6 paragraph [0050]-0051)). The combined

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administration includes simultaneous, sequential or separate administration of the PDE4 or PDE3/4 inhibitor on the one hand and the DMARD on the other hand, where the medicaments containing the PDE inhibitor and the DMARD are employed in the form of tablets, capsules, patches, suppositories, suspensions or solutions either together or separately and can be formulated with various excipients or vehicles suitable for desired pharmaceutical formulations (see the entire article, especially page 6 paragraph [0050-0053]; page 7 paragraph [0054]). The combined use (i.e. simultaneous, sequential or separate administration) of the PDE4 or PDE3/4 inhibitor and a DMARD may also include a medicament pack containing both the PDE4 or PDE3/4 inhibitor and a DMARD as discrete separate dosage forms and instructions for the simultaneous, sequential or separate administration of both discrete separate dosage forms (see the entire article, especially paragraph [0017]-[0020] and claims 1-6). Thus, the claims are readily envisioned by the composition taught by the reference.

Joensuu teach the treatment of rheumatoid arthritis by administering the combination of a compound of formula I with one or more disease modifying arthritis rheumatoid drugs (DMARDs). Examples of anti-rheumatoid arthritis drug (DMARD) can be an anti-inflammatory steroidal drug such as loteprednol etabonate.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

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Barsig does not teach the use loteprednol or a pharmaceutically acceptable ester as claimed by Applicant.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use loteprednol or a pharmaceutically acceptable ester

One of ordinary skill in the art would have been motivated to do this because Barsig teaches the combined administration of a PDE4 or PDE3/4 inhibitors, such as N-(3,5-dicholopyridin-4-yl)-2-[1-(4-fluorobenzyl)-5-hydroxy-1H-indol-3-yl]-2-oxoacetamide also known as AWD-12-281 with disease modifying anti-rheumatic drugs (DMARDs). Although Barsig does not teach specifically teach the use of loteprednol etabonate, it would have been obvious to one of ordinary skill in the art because loteprednol etabonate is a disease modifying anti-rheumatic drugs (DMARDs) used in the treatment of rheumatoid arthritis as suggested by Joensuu. Thus, it is an obvious variation of DMARDs that can be used in the treatment of rheumatoid arthritis. Therefore, the claimed invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made because the prior art is fairly suggestive of the claimed invention.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**.

See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristie L. Brooks whose telephone number is (571) 272-9072. The examiner can normally be reached on M-F 8:30am-6:00pm Est..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on (571) 272-0646.

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The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KB



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